

being unpatentable over Laustsen in view of Larsen and Heinsohn and further in view of Ward (Biotechnol 8:435-440, (1990)).

Objections

The Applicant submits that the USPTO's objection to the title is improper and an overly limiting to the Applicant's invention. The Applicant's invention is not limited to a "Method of Preparing An Aspartic Protease Free of Acid-Labile Enzymatic Activities" as suggested in the Office Action. This can be readily discerned from the specification. Further support for the current title may be found in the discussion of the § 112 rejections and throughout the application as originally filed.

The objection is respectfully traversed.

The Applicant wishes to thank the Examiner for noting that the heading was missing for "Brief Description of the Drawings." The applicant has requested that "Brief Description of the Drawings" be inserted into the application prior to the descriptions of Figures 1 and 2.

The objection is respectfully traversed.

35 U.S.C. § 112 ¶ 2

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-32 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, in sections 4-9 on pages 3-4 of the Office Action, the USPTO found the use of "reduced", "activity of the at least one desired polypeptide", "including", and the word "derived" in their respective claims indefinite. The Applicant appreciates the Examiner's suggestions and comments and believes that the amended claims address and overcome the Examiner's concerns.

The Applicant provides the following further discussion regarding the rejection.

The Applicant has provided consistent antecedent basis for the "activity" which the Applicant believes clarifies and addresses the Examiner's concerns. Applicant respectfully traverses the assertion in the Office Action that claims 20, 21, 27, 29, 31 and 32 are indefinite due to the recitation of "derived". It is well established that claims are definite if, "...read in light of the specification, [they] reasonably apprise those skilled in the art both of the utilization

and scope of the invention and if the language is as precise as the subject matter permits”. *Andrew Corp. v. Gabriel Electronics Inc.*, 6 U.S.P.Q. 2d 2010, 2013 (Fed. Cir. 1988) (quoting *Georgia-Pacific Corp. v. United States Plywood Corp.*, 118 U.S.P.Q. 122, 132 (2d Cir.) cert. denied, 358 U.S. 884 [119 U.S.P.Q. 501 (1958)]). The term “derived” means, in pertinent part, “to...obtain from a source of origin...”. (See, Webster’s Encyclopedic Unabridged Dictionary of the English Language, dilithium Press (1989), p. 389). Persons skilled in the art would readily appreciate both the utilization and scope of the invention of these claims. The enclosed Declaration of Peter Budtz supports Applicant’s position.

The rejection is obviated.

35 U.S.C. § 112 ¶ 1

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

On page 4 of the Office Action, section 10, claim 32, directed toward a method of producing aspartic protease from a naturally produced aspartic protease, was rejected for allegedly lacking written description in the specification because “the specification teaches only a two representative species of such aspartic proteases” and “fails to describe any other representative species by identifying characteristics or properties other than the functionality of being an aspartic protease.” (See, Office Action page 4).

Contrary to the USPTO’s assertion, the specification provides a teaching which is commensurate in scope with that of claim 32. The application as originally filed describes aspartic protease made by or derived from various organisms. For example, at page 8, lines 3-5, the inventor states that non-recombinant and recombinant microorganisms which are useful in the production of aspartic protease include bacterial species and yeast species, “...such as those mentioned above”. The yeast species “mentioned above” include “...fungal species *Rhizomucor miehei* and *Rhizomucor pusillus* and protease naturally-produced by the fungal species *Cryphonectria parasitica*...[and] other fungal species including *Rhizopus* species, *Physarum* species and *Pencillium* species, and *Bacillus* species.” (See, Appl. page 2, lines 27-32). This description of fungi is supplemented by the following disclosure of filamentous fungal species which can be used to make aspartic proteases: “...species of *Aspergillus*, e.g., *Aspergillus oryzae*, *Aspergillus nidulans* or *Aspergillus niger* including *Aspergillus nigervar*, *awamori*.[...] a

Fusarium species, e.g., *Fusarium oxysporum* or of a *Rhizomucor* species such as *Rhizomucor miehei* or a *Trichoderma* species including *Trichoderma reesei* and strains of *Cryphonectria* species including *Cryphonectria parasitica*...” (See, Appl. page 8, lines 9-14). Additional examples of organisms which can produce aspartic protease are described in the application on page 8, lines 26-30, which include for example a ruminant species including a bovine species, an ovine species, a caprine species, a deer species, a buffalo species, an antelope species and a giraffe species, a *Camelidae* species including *Camelus dromedarius*, a porcine species, an *Equidae* species and a primate species. Additional disclosure of various species is included in the working examples (such as, Examples 1 and 2).

On page 5 of the Office Action, section 11, claims 1-32 were rejected by the USPTO because “while being enabling for a method of preparing chymosin with reduced undesired glucoamylase, peptidase, amylase, cellulase, phosphatase, and protease activities by treating a non-acidophilic cell medium comprising said enzymes at a pH of 1.6 to 1.8 for a time sufficient to reduce glucoamylase, peptidase, amylase, cellulase, phosphatase and protease enzyme activities as compared to untreated glucoamylase, peptidase, amylase, cellulase, phosphatase, and protease enzymes, [it] does not reasonably provide enablement for a method of producing *any* desired polypeptide having reduced content of *any* enzymatic side activities by treating *any* medium with *any* pH of less than 2.0 as encompassed by the claims.” (See, Office Action, page 5). Further, the USPTO stated that the Applicant has “not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a method of producing *any* desired polypeptide having reduced content of *any* enzymatic side activities by treating *any* medium with *any* pH of less than 2.0 as encompassed by the claims.” (See, Office Action, page 6).

Applicant thanks the Examiner for noting that Examples 1 and 2 provide at least the scope of enablement which was alleged in the Office Action on pages 5 and 6. However, review of the specification indicates that the scope of enablement is broader than stated in the Office Action. For instance, the pH values specifically tested in Example 1 include pH of 1.15, 1.30, 1.48 and 1.61, in Example 2, pH of 1.6, 1.7 and 1.8, and in Example 3, pH of 1.7. The specification also discloses that the term “polypeptide” includes peptides of two or more amino acids, such as peptides, oligopeptides or proteins (See, Appl. page 4, lines 31-35), and raw materials and intermediate products used to manufacture final products containing the

polypeptides (*See*, Appl. page 5, lines 9-14). Examples of such polypeptides are preparations of enzymes made by extraction from tissues of higher organisms or made by cultivation of microorganisms, *e.g.*, milk clotting enzymes of animal and microbial origin using either organisms producing such an enzyme or using recombinant host microorganisms having an inserted gene expressing the milk clotting enzyme (*See*, Appl. page 5, lines 14-20).

The application also teaches that any starting or intermediate materials used to make a preparation containing a desired polypeptide or the final product can be used in the method of the invention. For example, at page 6, lines 30-35, there is described a media derived from the cultivation of microorganisms that, in the course of cultivation, produce one or more desired polypeptide and at least one undesired enzymatic side activity. A specific example of such media is identified as one derived from the cultivation of animal cells, plant cells and microbial cells, "...including cells of a bacterial species such as a gram negative bacterial species including *E. coli* and a gram positive species including a *Bacillus species*, a yeast species and a species of filamentous fungi" (*See*, Appl. page 7, lines 2-4). Further, the media is described as including those derived from the cultivation of cells of various yeast species, such as *Saccharomyces cerevisiae*, a methylotrophic yeast species, such as *Pichia pastoris* and a *Kluveromyces* species, and media derived from cultivation of species of filamentous fungi, such as *Aspergillus* species, *Cryphonectria* species, *Fusarium* species, *Rhizomucor* species and *Trichoderma* species (*See*, Appl. page 7, lines 6-9).

The specification also provides a disclosure of what constitutes "undesired enzymatic side activity". Such activity is identified as "any enzymatic activity, the presence of which in a polypeptide preparation is undesired for any reason such as detrimental or toxic effects occurring upon application or administration of the polypeptide preparation" (*See*, Appl. page 5, lines 24-27). Such undesired enzymatic side activities are exemplified by degradation of valuable components in a food product and immunologically adverse effects occurring when a pharmaceutically active polypeptide is administered, protease activity, starch degrading activity, peptidase activity, lipase activity, cellulase activity, lactase activity, hemicellulase activity, glucoamylase activity and phosphatase activity (*See*, Appl. page 5, lines 27-32).

As discussed above, the specification also provides a disclosure of how to make many other species of polypeptides with enzymatic activities, such as aspartic protease which may be an animal aspartic protease, including a mammalian aspartic protease, a plant aspartic protease

and a microbial aspartic protease. Example 3, provides a specific disclosure of how to make the claimed polypeptide from certain microbial and animal rennet products, i.e., Hannilase™ 195, a microbial coagulant produced by *Rhizomucor miehei*, Hannilase™ 2100, also a microbial rennet produced by *Rhizomucor miehei*, CHY-MAX™, a bovine chymosin produced by *Aspergillus niger var. awamori*, Modilase™ 195, an oxidised, thermolabile coagulant derived from *Rhizomucor miehei* and Thermolase™, a microbial coagulant produced by *Cryphonectria parasitica*. Examples 1-3 and general disclosure of the specification teach the applicability of the method of the claimed invention for other polypeptides with an enzymatic activity and other undesired enzymatic activities (such as starch degrading activity, peptidase activity, lipase activity, cellulase activity, lactase activity, hemicellulase activity, glucoamylase activity and phosphatase activity) (e.g., Appl. page 5, lines 31-32). The presence of the working examples in conjunction with other generic disclosure found in the remainder of the application instruct one skilled in the art how to carry out the claimed method for the described preparations.

As is well established under 35 U.S.C. § 112 ¶ 1, “the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” (*United States v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1986)). The factors to be considered in determining whether a disclosure would require undue experimentation include: “(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability of the art, and (8) the breadth of the claims.” *In re Wands*, 858 F.2d 731, 773 (1988).

Further, the court held in *In re Buchner*, that “a patent need not teach, and preferably omits, what is well known in the art.” 929 F.2d 660, 661 (Fed. Cir. 1991)[Emphasis Added].

In addition to the arguments set forth above, Applicant has included a Declaration by one of ordinary skill in the art, which clearly demonstrates that the specification includes a written description and enablement for the full scope of claims 1-32.

For all the reasons set forth above, it is submitted that claims 1-32 satisfy the requirements of 35 U.S.C. § 112, 1st paragraph.

35 U.S.C. §103(a)

(a) A patent may not be obtained through the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

On page 7, section 12 of the Office Action, the USPTO purports that claims 1-9, 12-22, 25-28 and 31 are obvious over Laustsen (U.S. Patent 6,080,564) in view of Larsen (WO 95/29999) and Heinsohn (U.S. Patent 5,215,908). Laustsen is said to teach “a method of obtaining a desirable enzyme with inactivated undesired enzyme activities by treatment with low pH”, whereas Larsen is viewed as teaching “that most commercially available milk clotting enzymes, containing primarily chymosin, are obtained by extraction from an animal stomach,” wherein following the “extraction process the pH of the extract is adjusted to as low as 0.5 using inorganic or organic acids in order to convert the inactive chymosin to an active form.” (See, Office Action, page 8). Heinsohn is viewed as teaching “that chymosin is industrially produced by fermentation of filamentous fungi that have been genetically modified to express and secrete chymosin.” (See, Office Action, page 8).

The USPTO, therefore, concludes that it would be obvious to “practice the method of Laustsen using an *Aspergillus* host cell expressing inactive chymosin and adjusting the pH of the resulting medium comprising inactive chymosin to 0.5.” Indeed, the USPTO alleges that “[o]ne would have been motivated to practice the method of Laustsen using an *Aspergillus* host cell expressing inactive chymosin and adjusting the pH of the medium to 0.5 in order to remove contaminating protease, amylase, and cellulase enzyme activities while holding the pH as acidic as possible for a desired polypeptide as taught by Laustsen, to convert the inactive chymosin to active chymosin as taught by Larsen, and to stop cell growth and fermentation as taught by Heinsohn, all in a single step.” (See, Office Action, page 9).

First, it is respectfully submitted that the “initial burden of establishing a basis for denying patentability to a claimed invention rests upon the USPTO.” (*In re Fines*, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988)). As stated by the Federal Circuit, “a proper analysis under 35 U.S.C. § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed

that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.” *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). In addition, the prior art reference(s) must teach or suggest all of the claim limitations. The teaching or suggestion to combine and the reasonable expectation of success must both be found in the prior art, and not in Applicant’s disclosure. *Id* at 493. *See also* M.P.E.P. § 2142. The Federal Circuit recently explained that “...the best defense against the subtle but powerful attraction of hindsight - based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.” (*In re Lee*, 61 U.S.P.Q. 2d 1430, 1433 (Fed Cir. 2002), quoting from *In re Dembiczak*, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999)).

Applicant initially notes that the claimed invention is directed toward a method of providing a polypeptide preparation having a content of undesired enzymatic side activities at such a level that they do not restrict *the* applicability of said polypeptide preparation for its intended purpose, by providing a medium having a pH of 2.0 or higher that comprises at least one desired polypeptide having an enzymatic activity and in addition at least one undesired enzymatic side activity, and subjecting said medium to a pH of less than 2.0 for a period of time that is sufficient to at least partially inactivate said at least one undesired enzymatic side activity.

Applicant submits that the claimed characteristics of the methods render patentable the claimed invention. Additionally, Applicant provides further arguments, which distinguish the claimed invention from the prior art of record.

Contrary to the assertions in the Office Action, one of ordinary skill in the art would not have had a reasonable expectation of success in deriving Applicant’s claimed invention from the cited references. While various methods exist to either purify or inactivate various enzymes and indeed in some cases amylase enzymes, prior to the Applicant’s discovery of the claimed invention it was not known that enzyme activity would survive at a pH below about 2.0. The cited references are directed toward a variety of enzymes and enzymatic activities, for instance, separating milk clotting enzymes (Larsen), purifying and recovering chymosin (Heinsohn), and inactivating labile proteases in media with *Aspergillus* species (Laustsen). In contrast, the Applicant’s claimed methods are designed and directed toward providing a polypeptide preparation having a content of undesired enzymatic side activities at such a level that they do not restrict the applicability of said polypeptide preparation, particularly at a pH lower than 2.0.

Initially, Applicant points out that the use of a pH below 2 in the context of treatment of enzymes is an uncommon practice, particularly for organic materials, such as proteins, sugars, and fats.

Laustsen discusses the need and means for improving stability during the processing and storage of *Aspergillus* protease against degradation by proteolytic side activity. Although amylase inactivation is discussed in examples 4 and 5, the inactivation occurred at pH 3.5 and 10.7 respectively. The use of the divergent pH's by Laustsen does not necessarily direct one to inactivate amylase activity at the lower pH taught by Laustsen. In fact, the teachings of Laustsen is likely to suggest to a person skilled in the art that a pH of 10.7 or a pH between 3.5 and 10.7 should be used, thereby teaching against the claimed invention. Additionally, even if one were to choose the lower pH used in Laustsen, there is no suggestion that a pH below 2.0 should or could be used without detrimental effects on the desired enzyme activity. This is particularly true since the enzymes of Laustsen are not likely to survive at a pH below 2. (*See*, attached declaration of Peter Budtz, ¶ 6).

Further, while Laustsen discusses using a pH as low as 2.0, this pH is insufficient to achieve the goals of the claimed invention. For example, a pH of 2.0 will not inactivate glucoamylase. (*See*, attached declaration, ¶ 7). Further, Laustsen inactivates amylase, a different enzyme from glucoamylase, and fails to suggest the inactivation of glucoamylase. Again, each time Laustsen inactivated amylase he used a pH of either 3.5 or 10.7.

As discussed above, Heinsohn relates to chromatographic purification of chymosin from unspecified enzymes and other impurities, and does not discuss glucoamylase or amylase activity or any other undesired activity. Further, the acid pre-treatment of pH 2-3 before chromatography according to example 1 is not sufficient to inactivate glucoamylase activity. In contrast, examples 1 and 2 of the present application show that a pH below 2.0, e.g. pH 1.8, inactivates glucoamylase activity.

Further, as discussed in the application on page 3, the purification of chymosin may contain "an undesirably high content of enzymatic side activities requiring a further separation step, e.g. chromatography, to remove these undesired activities." (*See*, Appl. page 3, lines 15-17).

Therefore, processes, such as Larsen's, "frequently result in unsatisfactory yields of milk clotting enzyme, in particular when the conductivity of the crude preparation, such as a filtrate of a microbial fermentation medium, that is applied to the chromatographic column is high. Another very significant problem associated with such processes is that also in such a process, the eluate

from the column may have undesired enzymatic side activities and thus a further chromatography step is required to remove such activities.” (See, Appl. page 3, lines 20-29).

Therefore, contrary to the USPTO’s assertion, one would not be motivated to look at the teaching of Laustsen, primarily using pH’s of 3.5 and 10.7; the teaching of Larsen, a process for separating milk clotting and restoration of chymosin; and the teaching of Heinsohn; related to purification of chymosin; to arrive at the claimed invention either used alone or in combination. One would particularly not be motivated to combine all of the teachings to achieve the claimed invention in a single step as suggested by the USPTO. (See, Office Action page 9).

Prior art references in combination do not make an invention obvious unless something in the prior references would suggest the advantage to be derived from combining their teachings. *In re Sernaker*, 217 U.S.P.Q. 1, 6 (Fed. Cir. 1983). In the present case, the Examiner has done no more than find the separate elements of the claimed invention and argue that broad disclosures which would require specific selection and experimentation to achieve the current invention, render the claimed invention obvious.

The rejection is respectfully traversed.

On page 9, section 13 of the Office Action the USPTO rejected claims 10, 11, 23, 24, 29, 30, and 32 as obvious over Laustsen in view of Larsen and Heinsohn and further in view of Ward. (Biotechnol 8:435-440, May 1990). The USPTO held that Laustsen, Larsen, and Heinsohn provide the teaching discussed in section 12, while Ward teaches “*Escherichia coli*, *Saccharomyces cerevisiae*, and *Yarrowia lipolytica* as successful hosts for the expression of prochymosin cDNA.” (See, Office Action, page 10.)

Initially, Applicant wishes to thank the Examiner for noting that neither Laustsen, Larsen, nor Heinsohn teach or suggest “a fusion protein comprising an aspartic protease and having an undesired enzyme activity or glucoamylase activity” or “expression of chymosin using the host cells of claims 10 and 11 or expressing a chymosin from the species of claims 29 and 30.” (See, Office Action, pages 9-10).

Applicant reasserts her statements above regarding the Larsen, Laustsen and Heinsohn references, and discusses the Ward reference. Initially, Applicant points out that the Ward reference does not suggest using a pH below 2.0. Ward is directed toward the production of chymosin using a fusion protein to increase production. Further, Ward utilized the low pH (pH down to 2.0) to release the chymosin from the fusion protein, and he found that the processing of

the fusion protein was actually inhibited at a pH of 2.0: “[p]rocessing of the fusion protein at pH 2 was inhibited by pepstatin, an inhibitor of chymosin and other aspartyl proteases.” (See, page 439, right column, upper part). Indeed, it appears that the fusion protein made by Ward had undesired enzymatic activity. (See, page 437, left column, lower part). As such, one would not be motivated to combine Ward with any or all of the above references to achieve the claimed invention.

The fact that a claimed product is within a broad field of the prior art and one might arrive at it by selecting specific items and conditions, does not render the product obvious in the absence of some directions or reasons in the prior art for making such selections. (*Ex parte Kuhn*, 132 U.S.P.Q. 359 (Pat. & Tr. Office Bd. App.)(1961)). Prior art references in combination do not make an invention obvious unless something in the prior references would suggest the advantage to be derived from combining their teachings. *In re Sernaker*, 217 U.S.P.Q. 1, 6 (Fed. Cir. 1983). In the present case, the USPTO has done no more than find the separate elements of the Applicant’s claimed invention and argue that broad disclosures which would require specific selection and experimentation to achieve the current invention, render the present invention obvious.

A combination may be patentable whether it be composed of elements all new, partly new or all old. *Rosemont, Inc. v. Beckman Instruments, Inc.*, 221 U.S.P.Q. 1, 7 (Fed. Cir. 1984). There must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination. *Lindemann v. Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 U.S.P.Q. 481, 488 (Fed. Cir. 1984). *Interconnect Planning Corporation v. Feil, et al.*, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). In the present case there is no such motivation. One cannot pick and choose among individual parts of assorted references to form a mosaic to recreate a facsimile of the claimed invention. *AKZO N.V. v. International Trade Commission*, 1 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1986). *Uniroyal v. Rudkin-Wiley*, 5 U.S.P.Q.2d 1434, 1438 (Fed. Cir. 1988).

If motivation were to exist, which it does not, one would not be motivated to select specific characteristics of Ward and/or Heinsohn, Larsen, and Laustsen and use them in combination given their distinctly different purposes with the expectation that they would provide the methods of the claimed invention. Further, one would not be motivated to utilize the method of providing a polypeptide preparation having a content of undesired enzymatic side

activities at such a level that they do not restrict the applicability of said polypeptide preparation, particularly at a pH below 2.0. Indeed, the statutory standard of 35 U.S.C. §103 is whether the invention, considered as a whole, would have been obvious to one of ordinary skill in the art, not whether it would have been obvious for one of ordinary skill in the art to try various combinations. *Akzo N.V. v. E.I. duPont de Nemours*, 1 U.S.P.Q.2d 1705, 1707 (Fed. Cir. 1987). Where the prior art discloses no particular preference for the component claimed from among a number of other components disclosed in a reference, i.e., where there is no disclosure within the prior art that would have led the routineer to make the critical selections to arrive at the claimed composition, the Board found a rejection for obviousness could not be sustained. *Ex parte Wittpenn*, 16 U.S.P.Q.2d 1730, 1731 (BPAI 1990).

Each of the claims 2-32, and 35-39 is dependent claims on claim 1 respectively, and therefore incorporates all of the limitations of claim 1 in addition to the further limitations set forth in the dependent claims at issue. As stated above, a proper *prima facie* obviousness rejection requires that the prior art reference(s) must teach or suggest all of the claim limitations. For the reasons set forth above, Ward, Heinsohn, Larsen, and Laustsen do not render obvious the claims. As stated in the M.P.E.P., “[i]f an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious.” *See* M.P.E.P. § 2143.03 (citing *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988)).

For all the reasons discussed above, Applicant’s claims are patentable in view of the references of record. Applicant also enclosed a Declaration by a person skilled in the art which buttresses Applicant’s contention of patentability of his claims. The rejection is respectfully traversed.

CONCLUSION

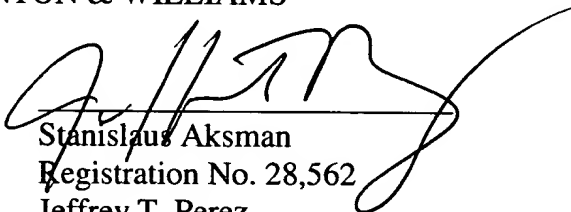
Applicant asserts that the application is in condition for allowance. Reconsideration and allowance of all pending claims is respectfully requested. Should any outstanding issues remain, the Examiner is invited to telephone the undersigned at 202-955-1926.

Respectfully submitted,

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Dated: Oct 9, 2002

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